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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/818,991	03/28/2001	Maurice Zauderer	1821.0050004	9763
26111	7590	01/27/2005	EXAMINER	
STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			PONNALURI, PADMASHRI	
			ART UNIT	PAPER NUMBER
			1639	

DATE MAILED: 01/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/818,991

Applicant(s)

ZAUDERER ET AL.

Examiner

Padmashri Ponnaluri

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10, 22-30, 43-62, 64-68, 73-109 and 138 is/are pending in the application.
- 4a) Of the above claim(s) 89-109 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10, 22-30, 43-62, 64-68, 73-88 and 138 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 March 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 10/18/04, 10/25/04
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

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### DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/18/04 has been entered.
2. Claims 11-21, 31-42, 63, 110-137 have been canceled and claims 1-10, 22-30, 43-62, 64-68, 73-109, 138 are currently pending in this application.
3. Claims 89-109 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 9/11/03.
4. Claims 1-10, 22-30, 43-62, 64-88 and 138 are currently being examined in this application.

### *Oath/Declaration*

5. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

The specification indicates priority to several provisional applications. However, the oath/declaration does not acknowledge the priority to the provisional applications. A new

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oath/declaration is required in the body of which the present application and priority applications, should be identified by application number and filing date.

Applicants in the response filed on 10/18/04 state that the 'specific reference claiming the benefit of a prior provisional application should appear in the first sentence of the specification and/or in the application data sheet.'

Examiner agrees with the applicants that the 'by providing the domestic priority information in the application data sheet (§ 1.76) constitutes the specific reference required by 35 U.S.C. 119(e) and need not otherwise be made part of the specification.' However, in the instant application, the oath/declaration does not include the priority to provisional application.

Applicant's arguments that the application data sheet (1.76) and the specification disclosure in the first sentence, provide priority provisional application data is not sufficient. Applicants are requested to provide a new oath and/or declaration with the priority information.

### ***Specification***

6. The objection to the specification set forth in the previous office action has been withdrawn in view of the amendments to the specification.

### ***Withdrawn Claim Rejections***

7. In view of the amendments to the claims the art rejection of claims under 35 U.S.C. 102(b) as being anticipated by US Patent 5,712,115 (HAWKINS et al), set forth in the previous office mailed on 6/16/04 has been withdrawn.

8. In view of the amendments to the claims, the rejections of claims under 35 U.S.C. 102(e) as being anticipated by Zauderer (US Pub No 20030133917 A1), set forth in the previous office mailed on 6/16/04 has been withdrawn.

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9. The new matter rejection and written description rejection set forth in the previous office action has been withdrawn in view of applicants' response.

*Claim Rejections - 35 USC § 112*

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 1-10, 22-30, 43-62, 64-68, 73-88, 138 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is written description rejection.

The instant claim briefly recites a method of selecting a target polynucleotide comprising, a) introducing into a population of mammalian host cells a library of insert polynucleotides; the library is constructed in a poxvirus vector or a adenovirus vector or a herpesvirus vector; and the expression of target polynucleotide in the host cell promotes cell death; b) culturing the host cells and c) collecting the insert polynucleotides from host cells, and the cell death is not the result of a cytotoxic T lymphocyte induced lytic event.

The instant specification discloses the use of linear DNA virus vector such as vaccinia virus vector, and the cell death is the result of expression of a suicide gene product by the host cell. The specification discloses the 'tri-molecular recombination' method in the method of

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identifying the target polynucleotide. The specification discloses that the suicide gene product is diphtheria toxin A subunit.

The specification discloses 'tri-molecular recombination' using modified vaccinia virus vectors. The specification discloses that vaccinia virus vectors currently are not used for identifying genes of interest from cDNA or other library, because high efficiency, high titer producing cloning does not exist in vaccinia (i.e., see 0324). The specification further discloses 'tri-molecular recombination is novel, high efficiency, high titer producing method of cloning vaccinia virus (i.e., see 0325). The specification examples of non-catalytic CD4+ T lymphocytes are all drawn to use of vaccines virus vectors in trimolecular recombination method, and suicidal gene. The specification description is directed to the use of specific Vaccinia virus vectors (especially vaccinia WR vectors) in trimolecular --recombination method, which clearly do not provide an adequate representation regarding the open ended claimed method for selecting a target polynucleotide of the instant claims. The specification description is directed to hypothetical methods of selecting target polynucleotides using trimolecular recombination method in selecting polynucleotides. The specification has no working examples of the instantly claimed method using the library of either pox virus vectors, adenovirus vector or a herpes virus vector, which is inserted into mammalian cells and collecting inserted polynucleotides from the dead host cells, and the cell death is not the result of a cytotoxic T lymphocyte induced lytic event.

With regard to the description requirement, Applicants' attention is directed to The Court of Appeals for the Federal Circuit which held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula [or] chemical name,' of the claimed subject

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matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, 1405 (1997), quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original)[The claims at issue in *University of California v. Eli Lilly* defined the invention by function of the claimed DNA (encoding insulin)].

Although directed to DNA compounds, this holding would be deemed to be applicable to the instant method of screening; which requires a representative sample of showing of sufficient identifying characteristics of the products used to demonstrate possession of the claimed generic(s) and to demonstrate possession of products identified using the claimed method. In the present instance, the claimed invention contains no identifying characteristics regarding the identified polynucleotide or the library of insert polynucleotides used.

Additionally, the narrow scope of examples directed to the use of specific vaccinia virus vectors in tri-molecular-recombination method, which are clearly not representative of the scope of the presently claimed method.

### ***Response to Arguments***

12. Applicant's arguments with respect to claims 1-10, 22-30, 43-62, 64-68, 73-88, 138 have been considered but are moot in view of the new ground(s) of rejection.

Applicants response has addressed the support for the limitation 'wherein cell death is not the result of cytotoxic T lymphocytes induced lytic event' and the use of different mammalian host cells has been fully considered. However, the response has not addressed the use of only tri-molecular recombination method, and specific vaccinia virus vectors.

### ***Conclusion***

13. The information disclosure statement filed on 10/18/04 has been fully considered and entered into the application. The references AT19-AR22 have been considered and are crossed

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since these documents have been considered as official documents of several different applications.

14. The following is a statement of reasons for the indication of allowable subject matter:

The use of vaccinia WR vectors and trimolecular recombination method used in identification of suicidal target polynucleotides is neither known nor suggested by the prior art.

15. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padmashri Ponnaluri whose telephone number is 571-272-0809. The examiner is on Increased Flex Schedule and can normally be reached on Monday through Friday between 7 AM and 3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
PADMASHRI PONNALURI  
PRIMARY EXAMINER

Padmashri Ponnaluri  
Primary Examiner  
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24 January 2005